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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,633

04/09/2004

Zia Yassinzadeh

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02/05/2009

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EXAMINER

DANG, PHONG SON H

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

02/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,633	YASSINZADEH, ZIA	
	Examiner	Art Unit	
	SON DANG	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/02/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed June 16, 2008 has been entered. Claims 1-11, 14 and 17-21. The previous 35 USC 112 rejections of claim 1 is withdrawn in light of Applicant's amendments to claims 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 5-6, 8, 10-11, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Zucker (U.S. Patent No. 2003/0055454). Zucker discloses the invention as claimed including a method for hemostasis of a puncture site (see Fig. 3A-3L) including providing a locating member (ref. 128) having an expansible member (ref. 124) on its distal end, a compression member (ref. 102) with an expansible element (ref. 150) on its distal end, inserting the locating member (Fig. 3B) through a sheath (ref. 304) to within a vessel, expanding the expansible member and drawing the locating member proximally (Fig. 3C-3F), removing the sheath from the tissue tract (Fig. 3G), advancing the compression member over the locating member (see ref. 102 over ref. 128) and expanding the expansible element on the other side of the puncture tract from the expansible member (Fig. 3G), the expansible element being engageable with

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subcutaneous tissue surrounding the vessel wall (Fig. 3H), the expansible element being a balloon (ref. 150) , inflating a distal face of the balloon at an angle to the compression member, unfolding concentric folds of the balloon (see the folds of ref. 150 from Fig. 3F to Fig. 3G), inflating the balloon to a deployed configuration having a concave distal end, and contracting and withdrawing the locating member while the compression member remains in place (Fig. 3H-3I).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 3-4, 7, 9, 14, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucker. Zucker do not disclose the predetermined distance, expanding the balloon to a conical configuration, the distal end of the balloon having a concave distal end, the expansible member deployed diameter, imaging the element during positioning, delivering energy to the puncture site, delivering a clot promoting agent or an anti-infection agent to the puncture site, or instructions on how to use the

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device. It would have been an obvious design choice to have modified the balloon of Zucker to have a conical shape and to have a distal concave end. Both of these design alterations are well-known in the art and would, therefore, be obvious to modify the balloon of Zucker to meet the design limitations. It would also be obvious to modify the predetermined depth of the expandable balloon in the tissue tract as well as to modify the expansible members diameter in order to fit the correct size puncture and provide enough pressure to cause hemostasis to occur. It is well-known in the art to image an insertion area in order to determine the exact location of where the device is moving through the tissue. It is also well-known in the art to use some form of energy for either imaging purposes or to seal the puncture site. It is further well-known in the art to use both clot promoting agents and anti-infection agents to help seal a wound/puncture in a vessel. It would be obvious to provide instructions on how to use the device of Zucker in order to allow a user to properly insert it and use it within and around a vessel.

Response to Arguments

4. Applicant's arguments filed June 16, 2008 have been fully considered but they are not persuasive. The applicant argues that the locating member 102 can not be advanced over handle portion/locating member 128. However, Fig. 3B of Zucker shows that handle portion 128 also runs down along central bore 120 and have a smaller circumference than the locating member/main shaft 102. Therefore, main shaft 102 can be advanced over handle portion 128. Applicant argues that balloon 124 and 150 can only be advance as a single unit. However, this argument is not supported by the claim languages. Moreover, balloon 124 is being push through the blood vessel by locating

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member 128 with balloon 150 remains in the subcutaneous tissue. Therefore, these balloon, 124 and 50, are moving independently with each other.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 5,728,134 to Barak teaches a method and apparatus for hemostasis.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809. The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SD

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773